REMARKS

This document is filed in reply to the Office Action dated May 26, 2004 ("Office Action"). Applicants have correct a typographical error, two occurrences, in the specification; namely, "hemagglutinin-neuraminidase gene" should read "hemagglutinin gene." Support for this correction can be found, e.g., at page 9, lines 6-11; page 15, Table 2; and page 16, lines 11-12.[1]

Applicants have cancelled claims 1-3, 6, 9-11, 13, 16, and 27. This cancellation has necessitated rewriting of claims 4, 7, and 12 in independent forms and incorporating into these three claims the limitations recited in claims 1, 6, 9, and 27. Applicants have also narrowed claims 4, 7, and 12, drawn to nucleic acid sets, by limiting the nucleic acid length ranges to 14-40 or 20-200 nucleotides. Support for "14-40 nucleotides" can be found, e.g., in original claim 1. Support for "20-200 nucleotides" can be found at, e.g., page 2, line 23 of the specification. These amendments have entailed cancellation of claims 13 and 16, narrowing of claim 15, and dependency change to claims 14 and 17. No new matter has been introduced.

The amendments should be entered as they raise no new issues that will require further consideration or search and also do not touch the merits of the application within the meaning of 37 C.F.R. § 1.116(b).

Claims 4, 5, 7, 8, 12, 14, 15, and 17-26 are pending. Among them, claims 18-26 have been withdrawn from further consideration for being drawn to a non-elected invention. Upon entry of the proposed amendments, claims 4, 5, 7, 8, 12, 14, 15, and 17 are under examination. Reconsideration of this application is requested in view of the following remarks:

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[1] These two passages provide support for this correction. They each discuss PCR primers (e.g., SEQ ID NOs: 20-23) and oligo-nucleotides (e.g., SEQ ID NOs: 50-52) selected from the influenza virus B genome. As shown at page 9, lines 6-11, the primers SEQ ID NOs: 20-23 are derived from the hemagglutinin gene region, rather than the hemagglutinin-neuraminidase gene region, of the influenza virus B genome. The oligo-nucleotides SEQ ID NOs: 50-52 are used to probe PCR products amplified from the influenza virus B genome by the primers. See page 15, Table 2; and page 16, lines 11-12. It follows that SEQ ID NOs: 50-52 must also be selected from the hemagglutinin gene region, rather than the hemagglutinin-neuraminidase gene region, of the influenza virus B genome.

Rejection under 35 U.S.C. § 112, first paragraph

The Examiner rejected claims 1-3, 6, 9-11, and 27 for failing to meet the written description requirement. See the Office Action, page 2, lines 14-17. Applicants have cancelled these claims, thereby rendering the rejection moot.

Rejection under 35 U.S.C. § 112, second paragraph

The Examiner rejected claims 1-17 and 27 for indefiniteness. According to the Examiner, "[i]n the sequence listing of elected SEQ ID NOs: 20, 35, 38, 39, 49, and 50, there are ambiguity codes such as K meaning G or T/U as well as other codes. However, the claims are indefinite as to whether they are intended to encompass a mixture of primers for the primers with ambiguity codes or a single primer with one of the two sequences." See the Office Action, page 7, lines 5-8. In the response filed on April 12, 2004, Applicants already pointed out that the specification teaches that each of the listed sequences represents one particular primer or probe instead of a mixture.

In this connection, Applicants would like to remind the Examiner that "[w]hether a claim is invalid for indefiniteness depends on whether those skilled in the art would understand the scope of the claim when the claim is read in light of the Specification." *North American Vaccine Inc. v. American Cyanmid Co.*, 28 USPQ2d 1333 (Fed. Cir. 1993). One skilled in the art, when reading the claims in the light of the specification, would be reasonably apprised of the scope of primers,. Thus, the claims at issue meet the definiteness requirement.

Rejection under 35 U.S.C. § 102(b)

The Examiner rejected claim 9 for being anticipated by Zuckerman et al., J. Virol. Methods (1993) 44:35-44. See the Office Action, page 9, lines 8-9. Applicants have cancelled claim 9.

Rejection under 35 U.S.C. § 103(a)

The Examiner rejected claims 1-17 and 27 for obviousness on two grounds. Applicants address each ground below:

I

The Examiner rejected claims 1-3, 6, 9-11, and 27 as being obvious over four references. See the Office Action, page 11, lines 1-5. Applicants have cancelled these claims.

II

The Examiner rejected claims 4, 5, 7, 8, 12-17, and 27 as being obvious over Grondahl et al., J. Clin. Microbiol., 1999, 37(1):1-7 ("Grondahl") in view of Echevarria et al., J. Clin. Microbio.,1998, 36(5): 1388-1391 ("Echevarria"), Osiowy et al., J. Clin. Microbio. 1998, 36:3139-3154 ("Osiowy"), Zuckerman et al., J. Virol. Methods, 1993, 44:35-44 ("Zuckerman"), Buck et al., Biotechniques, 1999, 27(3): 528-536 ("Buck"), U.S. Patent 5,374,717 to Rota et al., ("Rota"), and 6 GenBank Accession NOs, i.e., X55803, X57559, M18759, M73260, M11486, and M12594. See the Office Action, the paragraph bridging pages 14 and 15.

These rejected claims, drawn to nucleic acid sets, recite one or more of SEQ ID NOs: 1-57. According to the Examiner, (i) Rota and the 6 GenBank Accession NOs teach sequences that cover these SEQ ID NOs; and (ii) Buck supports that all nucleic acids selected from the prior art sequences would be expected to function as primers. As such, he concluded that "[i]t would be prima facie obvious to one of ordinary skilled in the art ... to combine [Grondahl, Echevarria, Osiowy, and Zuckerman and to select primers] from the sequences of GenBank and U.S. Patent 5,374,717" to make SEQ ID NOs: 1-57. In other words, Examiner believes that the cited prior art references suggest a genus of nucleic acid sets encompassing the claimed nucleic acid sets, thereby rendering the claims obvious.

Applicants disagree and would like to remind the Examiner that "[t]he fact that a claimed species or subgenus is encompassed by a prior art genus is not sufficient by itself to establish a prima facie case of obviousness. ... Some motivation to select the claimed species or subgenus must be taught by the prior art." (MPEP 2144.08).

Independent claim 4 covers a set of nucleic acids including three pair of primers, which contain, among others, (i) SEQ ID NOs: 5 and 7; (ii) SEQ ID NOs: 24 and 26; and (iii) SEQ ID NOs: 12 and 14, respectively. It is the Examiner's position that the sequences of GenBank Accession NOs: X57559, M73260, and M11486 cover the three pairs of SEQ ID NOs, respectively.

To facilitate discussion, Applicants focus on SEQ ID NOs: 5 and 7, and GenBank Accession No X57559. According to the Examiner, GenBank Accession No X57559 teaches a 15,646-nucleotide parainfluenza type 2 virus sequence that includes SEQ ID NOs: 5 and 7.

First, Applicants note that SEQ ID NOs: 5 and 7 are 22 and 24 nucleotides in length, respectively. On the other hand, GenBank Accession No X57559 does not teach or suggest 22 and 24 nucleotides as lengths of primers. Thus, on this basis alone, it does not render SEQ ID NOs: 5 and 7 obvious.

Second, even if one skilled in the art would use 22 and 24 nucleotides as the lengths of primes, he or she would have to select SEQ ID NOs: 5 and 7 from a large number of candidates. Indeed, GenBank Accession No X57559 contains 15,625 different 22-nucleotide sequences (15,625 = 15646-22+1) and 15,623 different 24-nucleotide sequences (15,623 = 15,646-24+1). Thus, to select SEQ ID NOs: 5 and 7 from it, one would have to choose from myriads of candidates, i.e., 244,109,375 (244,109,375 = 15,625x15,623) pairs of primers.

By the same token, given GenBank Accession NOs: M73260 and M11486 (35,935 and 8,516 nucleotides in length, respectively), one skilled in the art would have to choose SEQ ID NOs: 24 and 26 (16 and 17 nucleotides in length, respectively) from 1,290,210,480 candidates, and SEQ ID NOs: 12 and 14 (21 and 23 nucleotides in length, respectively) from 72,165,024 candidates.[2]

Thus, to select a set of nucleic acid of claim 4, which contains the just-described three pairs of SEQ ID NOs, one would have to choose from about 2.27×10^{25} candidate sets (2.27×10^{25} = 244,109,375x1,290,210,480x72,165,024). Since the references cited by the Examiner do not

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[2] 1,290,210,480 = (35,935-16+1)x(35,935-17+1)
72,165,024 = (8,516-21+1)x(8,516-23+1)

provide "[any] motivation to select the claimed [nucleic acid set] species or subgenus" from such an astronomical number of candidates, they do not render claim 4 obvious.

Independent claim 7 is drawn to a set of nucleic acids including three nucleic acids that are amplified with three pairs of primers, respectively. These three pairs of primers contain, among others, respectively, SEQ ID NOs: 12 and 14, SEQ ID NOs: 16 and 18, and SEQ ID NOs: 20 and 22. Independent claim 12 is also drawn to a set of nucleic acids including three nucleic acids, which are selected from SEQ ID NOs: 40-52.

According to the Examiner, (i) the sequences of GenBank Accession NOs: M11486 and M12594, and that disclosed in Rota (856, 8516, and 1080 nucleotides in length, respectively) cover SEQ ID NOs: 12 and 14, SEQ ID NOs: 16 and 18, and SEQ ID NOs: 20 and 22 (21, 23, 22, 22, 22, and 22 nucleotides in length, respectively); and (ii) the sequence of GenBank Accession NO M18759 (1882 nucleotides in length) and that disclosed in Rota cover SEQ ID NOs: 39 and 50 recited in claim 12 (34 and 27 nucleotides in length, respectively). For the same reasons set forth above, claims 7 and 12, like claim 4, are non-obvious over the cited documents. So are claims 5, 8, 14, 15, and 17, all of which depend from claim 4, 7, or 12.[3]

CONCLUSION

Applicants submit that the rejections asserted by the Examiner have been overcome, and that the claims, as amended, define subject matter that is definite, sufficiently described, novel, and non-obvious. Allowance of this application is therefore proper, and early favorable action is solicited.

[3] Claims 13 and 16 have been cancelled, and therefore are not addressed.

Please apply any other charges or credits to deposit account 06-1050.

Respectfully submitted,

Date: 8-17-04

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